REMARKS

Responsive to the Office Action mailed March 23, 2006 and with an extension of time of three months, the present paper is timely filed on or before September 23, 2006. By the present Amendment, no claims are cancelled and claims 90 and 93 are amended. Accordingly, claims 90 - 96 are in the Application. Entry of the amendments and reconsideration of the Application are respectfully requested.

The Claim Amendments

Claims 90 and 93 are amended to recite numerical limits on the amount of superdisintegrant and tannic acid in the composition. Applicants respectfully submit that support for the amendments can be found I the specification at, for example, page 13, lines 27 - 28 and throughout the specification.

Applicants respectfully submit that the amendments do not introduce new mater into the Application.

Claim Rejections Under 35 U.S.C. § 103

Claims 90 - 96 were rejected under 35 U.S.C. § 103 as allegedly obvious over Burnside et al. , United States Patent 6,322,819 (hereafter Burnside et al.) in view of Swanson et al., United States Patent 4,326,525 (hereafter Swanson et al.). Because there is no motivation to combine Burnside et al. and Swanson et al., because, even *if* combined, the references neither teach nor suggest all of the limitations of Applicants claims, and further because, even *if* combined with each other and knowledge available in the art at the time the present invention was made, the applied references do not provide an enabling disclosure of Applicants' inventive rapidly-swelling dosage forms, Applicants respectfully traverse.

Burnside et al. discloses an oral pulsed drug delivery system (compositions). The compositions disclosed by Burnsides et al. provide for immediate release and a later release (hence 'pulsed release), which later release can be enteric release[1]. The drug in the system of Burnside at al can

1 Burnside et al. at 3:49 to 3:51 and further at 7:51.

be methylphenidate

The drug delivery system (composition) of Burnside et al. comprises 'cores' that have the drug included in or coated on them[2]. At column 6, beginning at line 57 and continuing to column 7, line 19, Burnside at al. rattles-off a laundry list of numerous materials of a variety of genres that can be used to make the 'pellets' (i.e. cores) of the delivery system therein disclosed. The pellets (cores) are then coated with either or both of a protective layer and an enteric coating, in any order. Applicants understand that all pellets (cores) of the system of Burnside at al. are coated[3]. This coating arrangement is essential to the drug delivery system in Burnside et al[4].

Swanson et al. discloses an osmotic device - essentially a 'mini-pump' that can be swallowed or implanted. The osmotic device delivers beneficial agent (drug) that is housed in a compartment[5]. Tannic acid can be included in the osmotic device in combination with the beneficial agent, not in combination with polymer such as that in the shell of the osmotic device.

The present invention, as claimed, is an oral dosage form comprised of a homogeneous solid matrix that meets a specific swelling limitation[6]. There is no 'compartment' as in the osmotic device of Swanson et al. The solid matrix that is the gastric retention vehicle composition of the present claims can comprise, for example, crospovidone, croscarmelose sodium (i.e. Ac-Di-Sol®), or crosslinked PVP in a specified relative amount. The superdisintegrant of Applicant's invention must be part of the matrix and in facile contact with gastric fluid, not isolated in a coated "core" as disclosed in Burnside et al.

The homogeneous matrix or gastric retention vehicle composition of the present invention also contains tannic acid in a specified relative amount. Tannic acid is not taught or suggested in Burnside et al. Tannic acid, in an

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2 Burnside et al. at 7:45 - 48.
3 *See, e.g.,* Figure 2A and discussion thereof in the specification.
4 *See, e.g.,* Burnside et al. at 4:15 - 48.
5 *See* ***14*** of Figure 2.
6 Functional limitations are still limitations and cannot be ignored. A functional limitation must be evaluated and considered, just like any other limitation of the claim. M.P.E.P. § 2173.05(g).

undisclosed amount, is taught in Swanson. But in the osmotic device of Swanson any tannic acid is in admixture and co-dispensed *in situ* with the drug to improve its bioavailability (Applicants assume that this improvement is through chemical interaction, such as salt formation, or by a local buffering effect).

Burnside et al. disclose a drug delivery system (composition) that can include, e.g., Ac-Di-Sol® as a component of the cores[7], all of which are coated. *See* Figure 2A of Burnside et al. Because the cores are coated, the Ac-Di-Sol® (or any other polymeric composition that is a superdisintegrant, as Applicants use that term) would not be in facile contact with gastric fluid when swallowed and would not participate in rapid swelling of the composition as a whole, an express functional limitation of Applicants' claims. Swanson et al. disclose an osmotic device that can have tannic acid in it. But the tannic acid in Swanson et al. acts locally, *in situ*, by interaction with the drug[8]. The drugs (beneficial agent) of Swanson et al. are, apparently, in highly concentrated form. The Office has not pointed to any motivation to use the tannic acid of Swanson et al. in the system of Burnside et al., other than to, allegedly, produce and provide a multiple pulsed dose of e.g., methylphenidate[9]. But Burnside et al. purports to do that without tannic acid[10] and there is no suggestion that putting tannic acid in the solid cores would be reasonably expected to produce a beneficial effect.

Moreover, apart from utility for administering a drug, the system of Burnside at al. and the osmotic device of Swanson et al. are completely different. In Burnside et al. the drug is on or in a solid core that is coated and released when the coating is ultimately breached. In Swanson et al., the beneficial agent is enclosed in a compartment and dispensed under the action of osmotic pressure. The two articles are completely different and, Applicants respectfully submit, the Office has not proffered any argument why the skilled artisan of the day would have had even the remotest motivation to combine the tannic acid of Swanson et al. into the cores (pellets) of Burnside et al. For

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7 Burnside at al. at 7:2.
8 Swanson et al. at 8:48 to 9:14.
9 Office Action, page 3, 4th full paragraph.
10 Burnside et al., abstract.

this reason alone, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Moreover, even *if* the teachings of the applied references *were* combined - which Applicants respectfully submit is improper in and of itself - the combined references do not teach or suggest all of the limitations of Applicants' claims, in particular the relative amounts of superdisintegrant and tannic acid. For this additional reason, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Furthermore, neither Burnside et al. nor Swanson et al., alone or in any combination, would have enabled the skilled artisan of the day to make the inventive, swelling, gastric-retentive drug delivery vehicle of Applicants' claims. Burnside et al. merely recites a laundry list of different materials, mostly polymeric, that cold be used for the "cores" therein disclosed. Burnside et al. does not provide any teaching on selecting particular combinations of these materials or on the relative amounts if a combination is used. Applicants were the first to do so. Applicants respectfully submit that the near encyclopedic manner in which Burnside et al. discloses the materials that can be used in the system therein disclosed would have suggested to the skilled artisan of the day that kinds and relative amount of the various materials were wholly irrelevant. Even *if* the skilled artisan of they day *were* to decide, on a lark, to put tannic acid together with two materials from Burnside et al. (at least one being a superdisintegrant as Applicants use that term), he would have been absolutely clueless as to where to start and as to how much of each ingredient to use to make a gastric retention vehicle that met all of the limitations of Applicants' claims. For this additional reason, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Conclusion

Based on the foregoing amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance, which allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to call the undersigned attorney.

PETITION FOR EXTENSION OF TIME

Applicants hereby respectfully petition under 37 C.F.R. § 1.136 for an extension of time to reply of THREE MONTHS , the fee required under 37 C.F.R. § 1.17 therefor is paid herewith.

AUTHORIZATION TO DEBIT

The Commissioner is hereby authorized to debit deposit account 11-0600 in the amount of $ 1, 020 for the fee due under 37 C.F.R. § 1.17(a)(3). Applicants respectfully submit hat no additional fees are due with this paper. If additional fees are due, the Commissioner is hereby authorized to debit deposit account 11-0600 for any additional fees due.

Respectfully submitted,

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